REMARKS

Claims 21-52 are currently pending in this application. Claims 21-52 are canceled and new claims 53-64 have been added. The Examiner has restricted the first compound of the claims to lysine. New claims 53-64 also recite only lysine and thus maintain this restriction requirement. No new subject matter is believed to have been added by this amendment.

Claims 21-52 stand rejected under 35 U.S.C. 112, first paragraph, for purported lack of enablement. The Examiner asserts that the specification does not provide reasonable enablement for "positively charged compounds." Claims 21-52 have been cancelled and new claims 53-64 no longer recite "positively charged compounds," thus mooting this rejection.

Claims 21-52 stand rejected under 35 U.S.C. 112, second paragraph, for purported indefiniteness. The Examiner asserts that claims 21 and 37 recite the broad recitation "substances" along with the narrower recitation "in particular proteins or peptides," thus rendering the claims indefinite. Claims 21-52 have been cancelled and new claims 53-64 no longer recite the broad recitation "substances," thus mooting this part of the rejection. The Examiner further asserts that "carboxyl derivatives" render the claims indefinite as to the compounds encompassed by the claims. Applicants respectfully submit that it is a common practice in the art to administer, in addition to amino acids *per se*, pharmaceutically acceptable salts or carboxylic acid derivatives thereof. In particular, lysine typically is used as its carboxylic acid derivative, monoacetate. Thus, those skilled in the art would know precisely what compounds are encompassed by the recitation "carboxyl derivatives" as it pertains to amino acids.

Claims 37-51 stand rejected under 35 U.S.C. 102(b) for purported anticipation by Takami et al.; claim 52 stands rejected under 35 U.S.C. 102(b) for purported anticipation by Madsen et al.; and claims 21-36 stand rejected under 35 U.S.C. 103(a) for purported unpatentability over Takami et al. The Examiner asserts that Takami et al. teach a composition containing 4-6 g of lysine and 4-7 g of arginine in 100 ml of parenteral solution. The Examiner further asserts that Madsen et al. teach a method of administering a lysine and arginine-containing composition to renal failure patients to treat renal failure and to protect the kidney

from further damage. Finally, the Examiner asserts that it would be obvious to incorporate lysine and arginine into one composition to form a parenteral solution.

The present invention as now claimed inheres in preparing a therapeutic composition that contains only two particular amino acids, lysine and arginine or lysine and ornithine, or their specified derivatives, in specific amounts that range from about 10 to 45 grams for each amino acid in a one liter infusion fluid for administration to a subject in order to inhibit renal uptake of proteins or peptides used for therapeutic or diagnostic purposes that may damage the kidneys of the subject.

In contrast, Takami et al. disclose a cocktail of eighteen amino acids, in which lysine and arginine are only two of the eighteen amino acids present in the cocktail. Furthermore, Takami et al. do not teach providing ornithine at all as one of the eighteen amino acids. Applicants submit, therefore, that the general disclosure of the eighteen amino acid cocktail of Takami et al. neither teaches nor suggests the specific combination of lysine and arginine or lysine and ornithine, nor does Takami et al. teach the specific dosage ranges of the above-cited two amino acid composition as now claimed.

Similar to Takami et al., Madsen et al. disclose a composition of a fifteen amino acid cocktail for treating renal failure or deficiency, in which lysine and arginine are only two of the fifteen amino acids present in their cocktail, with ornithine not being taught at all. Thus, the general disclosure of an amino acid cocktail of fifteen amino acids, in which lysine and arginine are only two of the fifteen amino acids, does not anticipate the particular two amino acid composition in the particular dosage ranges now claimed.

Furthermore, Applicants submit that it would not be obvious to one skilled in the art to prepare the particular amino acid composition of lysine and arginine, or lysine and ornithine, of the present invention as now claimed, from the general disclosure of the eighteen amino acid cocktail of Takami et al.

In conclusion, Applicants contend that Takami et al. and Madsen et al. neither teach nor suggest the particular unique two amino acid composition of lysine and arginine, or lysine and ornithine, or their pharmaceutically acceptable salts or carboxyl derivatives, in the particular dosage range, of the claimed invention.

For all the foregoing reasons, new claims 53-64 are patentable over the cited prior art and in condition for allowance. Withdrawal of the asserted rejections and allowance of all pending claims 53-64 is respectfully requested.

Respectfully submitted,

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